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May 25, 2004

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**COURIER**

Division of Dockets Management Branch  
Food and Drug Administration  
Rm. 1061 (HFA- 305)  
5630 Fishers Lane  
Rockville, MD 20852

Re: Docket No. 2004P-0223

Dear Sir or Madam:

Enclosed are four copies of replacement pages 30 and 32 for the Citizen Petition filed by General Mills, Inc. on May 11, 2004. These pages are being replaced due to inadvertent typographical errors.

If you have any questions, please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink, appearing to read 'Stuart M. Pape'.

Stuart M. Pape  
Counsel to General Mills, Inc.

2004P-0223

CR 1

prevent consumer confusion, by providing a simple and consistent standard for food labeling. The FDA also explained in the 1993 final rule that a definition for fresh and its related terms is necessary because of the consumer confusion that has resulted from its misuse and "that a regulatory definition will discourage such misuse and will allow the Agency to efficiently enforce the misbranding provisions of the Act, particularly Section 403(a), when the term is misused."<sup>103</sup>

Establishing these definitions also fits squarely with FDA's stated objective of increasing enforcement activities regarding consumer labeling.<sup>104</sup> By establishing a simple and consistent standard against which to evaluate whole grain label claims, FDA will better be able to ensure labels are accurate. Also, by publishing a consistent standard, FDA will encourage manufacturers to produce foods that satisfy the requirements of the claim. A consistent labeling standard will also make it easier for health professionals to guide consumers in their healthy food choices.

A substantial body of scientific evidence supports the descriptors for whole grain. There is a significant amount of scientific data attributing positive health benefits to whole grain. In addition, the proposed levels for the whole grain descriptors are based on sound scientific data and dietary guidelines established by public health agencies within DHHS and USDA. The whole grain descriptors take into account and complement the recommendations put forth by these public health agencies. Finally, consumer studies indicate that Americans are receptive to information about whole grain consumption, diet and health and these claims facilitate their goals. These data provide adequate evidence to support the use of these claims and the public health benefits that will be achieved through greater awareness of whole grain content in foods.

As discussed above, consumers are continually reminded through the health claims about products that contain whole grains and the numerous dietary guidance recommendations about whole grain consumption. However, consumption is still significantly below daily recommended servings. This is due, in part, to consumers' confusion about which products contain whole grains.

The two-step process establishing the proposed descriptors for whole grain, which is discussed in greater detail in the following section, provides immediate access to a mechanism to easily identify foods that contain a dietarily

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<sup>103</sup> 58 Fed. Reg. at 2402.

<sup>104</sup> Announcement of the CHIBN Initiative, December 18, 2002.

previous rulemaking document, FDA stated that whole grain may be interpreted as an implied nutrient content claim for fiber.<sup>105</sup> This position has discouraged manufacturers from communicating to consumers regarding whole grain, thereby providing no incentive for manufacturers to increase whole grain content in foods. In light of the mounting scientific evidence in favor of the health benefits associated with whole grain, FDA's outdated position about a presumed exclusive relationship between whole grain and fiber should be revised to reflect the current science and dietary guidance by recognizing the entire whole grain as a beneficial and unique substance, and providing a simple and consistent labeling message for manufacturers to use to communicate whole grain content to consumers.

Subsequent to the issuance of the guidance document, FDA may formalize its policy on the descriptors for whole grain by conducting informal rulemaking. In Attachment 1, proposed regulations for the descriptors are provided that establish appropriate whole grain levels to qualify for the claims, as well as corresponding compliance and test methodologies.

Through the guidance document, the Agency may use its enforcement discretion to ensure that food manufacturers are properly declaring the claims on their food labels. Compliance, which is discussed in more detail in the following section, will be determined using fiber as a surrogate to evaluate whether the product meets the requisite whole grain levels for the declared claim. Fair and regulated claims are essential for consumers to adopt and understand new labeling claims. Indeed, the purpose of the whole grain descriptors is to assist consumers in identifying food with dietarily significant amounts of whole grain. As FDA recognized in stressing the importance of enforcement to the CHIBN objectives, without vigilant enforcement of inappropriate use of the claims, the benefit to the public health obtained by increased consumption of whole grains will not be achieved.

Implementation of the descriptors for whole grain through the two-step process recognizes that public health is a priority and immediate action must be taken to provide consumers with direct and tangible benefits. Initiating the process through the guidance document allows consumers immediate access to the health and nutrition information of whole grains and allow them to apply

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<sup>105</sup> In the preamble to FDA's regulation implementing NLEA, FDA discussed the issue of "single nutrient implied claims." In its discussion, FDA stated its position that statements such as "contains oat bran" or "contains whole wheat" "would be nutrient content claims because they call attention to the fact that the product has been made with an ingredient that contains a valuable nutrient [fiber]," although FDA stated that it would evaluate such claims on a case-by-case basis. (58 Fed. Reg. 2302 at 2370).